EVALUATION OF RISK FACTORS OF CORNEAL GRAFT FAILURE IN PATIENTS UNDERGOING KERATOPLASTY

Protocol

MS OPHTHALMOLOGY

Submitted By

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(2023-2026)

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This is to certify that the protocol titled **"EVALUATION OF RISK FACTORS OF CORNEAL GRAFT FAILURE IN PATIENTS UNDERGOING KERATOPLASTY"** will be bonafide genuine research work carried out by **Dr. ANIMESH SINGH** in partial fulfilment of the requirements for award of the degree of M.S. in the speciality of ophthalmology.

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CERTIFICATE BY THE CO-GUIDE

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CERTIFICATE BY THE GUIDE

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Guide Sarita Aggarwal
Dr. SARITA AGGARWAL
Professor and Head of Department
Department of Ophthalmology
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CERTIFICATE BY THE HEAD OF THE DEPARTMENT

This is to certify that the protocol titled **"EVALUATION OF RISK FACTORS OF CORNEAL GRAFT FAILURE IN PATIENTS UNDERGOING KERATOPLASTY"** will be bonafide research work carried out by **Dr. ANIMESH SINGH** in partial fulfilment of the requirements for award of the degree of M.S. Ophthalmology will be based on bonafide work carried out by him under my guidance and supervision and is completed to my full satisfaction.

Sarita Aggarwal

PROF. (Dr.) SARITA AGGARWAL
M.B.B.S., M.S.
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SANTOSH
Deemed to be University
(Established u/s 3 of the UGC Act, 1956)

ENDORSEMENT BY THE DEAN OF THE COLLEGE

This is to certify that the protocol titled **"EVALUATION OF RISK FACTORS OF CORNEAL GRAFT FAILURE IN PATIENTS UNDERGOING KERATOPLASTY"** will be a bonafide research work carried out by **Dr. ANIMESH SINGH** under the esteemed guidance of **Dr. SARITA AGGARWAL** Santosh Medical college and is presented before the ethical committee of Santosh University, Ghaziabad for requisite approval.

Dr Alka Agrawal

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Content of Protocol

1. Introduction with need for study
2. Aims & Objectives
3. Review of Literature
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INTRODUCTION

The corneal bed and the anterior chamber are immune-privileged sites, but despite the relative immune privilege of the cornea as a transplanted tissue, the most common cause of corneal graft failure in all reports is allogeneic rejection.

Corneal transplantation, also known as keratoplasty, stands as one of the most common and successful organ transplant procedures worldwide. It offers a remarkable solution for restoring vision in individuals suffering from various corneal disorders such as keratoconus, corneal scarring, and endothelial dysfunction. Despite advancements in surgical techniques and postoperative care, corneal graft failure remains a significant challenge, leading to compromised visual outcomes and necessitating re-grafting in some cases.

A corneal graft is defined as rejected when it became edematous and showed such signs of immunological rejection as a rejection line, infiltratious keratic precipitates, or anterior segment inflammation. The diagnosis of rejection can be made only if the transplant had remained clear for at least 2 weeks after surgery.

Graft failure is defined as an irreversible loss of central graft clarity and is determined clinically using a slit lamp biomicroscope.

The multifactorial nature of corneal graft failure brings out the importance of identifying and understanding the various risk factors involved. While several studies have explored potential predictors of graft failure, there remains a need for comprehensive investigations that integrate diverse patient demographics, preoperative conditions, surgical variables, and postoperative outcomes.

The aim of this study is to analyse the risk factors associated with corneal graft failure in patients undergoing keratoplasty. and provide a simple evidence-based protocol for the prevention and treatment of corneal graft rejection.

NEED FOR STUDY

To Understand and address various risk factors which are crucial for optimizing outcomes and educating the patients about strict post-operative care. By developing the strategies that will educate the patients in managing the rejection that are critical to the survival of a corneal graft thus reducing the ocular morbidity due to corneal graft failure.

AIM:
Evaluation of risk factors of corneal graft failure in patients undergoing keratoplasty.

Objectives :

To find out the demographic factors that may influence graft failure rates.

To evaluate the preoperative factors

To analyse the various microbial and host factors

To study the post operative factors causing graft failure episodes.

To study management and prevention of corneal graft failure.

REVIEW OF LITERATURE

Gurnani B, Czyz CN, Mahabadi N, et al. Corneal Graft Rejection. [Updated 2023 Jun 11]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK519043/ : Despite the relative immune privilege of the cornea as a transplanted tissue (both the recipient corneal bed and the anterior chamber are immune-privileged sites), the most common cause of corneal graft failure in all reports is allogeneic rejection. In first-time graft recipients with no vascularisation of the recipient's corneal bed, 2-year survival rates exceed 90%; this decreases to 35% to 70% in recipients with high-risk factors for rejection. In one-third of all corneal grafts fail, signs of a destructive attack by the immune system have been observed. A rejection episode results in a loss of donor endothelial cells, which are critical for the maintenance of corneal transparency. This activity highlights the role of the interprofessional team in caring for patients with the challenge of corneal graft rejection.

Barraquer RI, Pareja-Aricò L, Gómez-Benlloch A, Michael R. Risk factors for graft failure after penetrating keratoplasty. Medicine (Baltimore). 2019 Apr;98(17):e15274. doi: 10.1097/MD.0000000000015274. PMID: 31027083; PMCID: PMC6831321. : The objective of our study was to define principal risk factors for graft failure in patients who underwent penetrating keratoplasty (PK).Retrospective data obtained from a cohort of 895 penetrating keratoplasties performed between 2001 and 2006 were analysed. Recipient related factors, graft characteristics, and surgical technique were assessed in a univariate analysis and with a multivariate proportional hazard model to detect principal risk factors for definitive graft failure.Multivariate analysis showed clear significance for diagnosis and number of previous grafts and border line significance for the oldest donor age group. Patients with keratoconus had the best 10-year survival estimate (95%), followed by endothelial and stromal dystrophies (both 55%), infectious leukomas (49%), trauma (33%) and chemical burns (14%). Primary PK grafts had a survival rate of 81%, second grafts of 33% and third or more grafts of 16%. Overall 10-year survival estimate based on univariate analysis was found to be 65%.In conclusion, we found that primary diagnosis and previous graft failures in the recipient are the most important risk factors of graft failure after a PK.

Yin J. Advances in corneal graft rejection. Curr Opin Ophthalmol. 2021 Jul 1;32(4):331-337. doi: 10.1097/ICU.0000000000000767. PMID: 33989234; PMCID: PMC9290782. : Immune rejection after corneal transplantation is a major risk for graft failure. We aim to summarize recent

advances in the understanding and management of graft rejection. Immune rejection remains the leading cause of graft failure in penetrating keratoplasty. While ABO blood type and sex match between donor and recipient may reduce rejection, human leucocyte antigens class II matching in a randomized study did not reduce the risk of rejection in high-risk penetrating keratoplasty. Compared with penetrating keratoplasty, deep anterior lamellar keratoplasty, descemet stripping automated endothelial keratoplasty, and descemet membrane endothelial keratoplasty have lower immune rejection rates of 1.7–13%, 5–11.4%, and 1.7–2.8%, respectively, based on long-term (5 years and more) studies. Whether immune rejection is a major risk factor for graft failure in these lamellar keratoplasties is unclear. While there have not been major advances in the systemic management of graft rejection, topical nonsteroid agents such as tacrolimus and anti-vascular endothelial growth factor (VEGF) have shown promise in high-risk cases. Immune rejection remains the leading cause of graft failure in penetrating keratoplasty. Lamellar keratoplasties have significantly lower rejection rates compared with penetrating keratoplasty. The significance of rejection in the failure of lamellar grafts warrants further investigation.

Shah PP, Hasan A, Winokur J, Braunstein R, Ritterband DC, Seedor JA, Cheela I. Impact of Donor, Recipient, and Graft Characteristics on Corneal Transplantation Outcomes. Clin Ophthalmol. 2023 Feb 23;17:633-640. doi: 10.2147/OPTH.S399847. PMID: 36866241; PMCID: PMC9970880. : Although several donor, recipient, and graft characteristics have been studied in relation to corneal transplantation outcomes, no study to our knowledge has assessed the impact of donor cooling times on postoperative outcomes longitudinally. With only one corneal graft available for every 70 needed worldwide, this study seeks to identify any factors that could alleviate this shortage. Among 111 transplants, our adjusted model found that DTC ≥4 hours was associated with significantly worse BCVA, but only at 6-month postoperative follow-up (odds ratio [OR]: 0.234; 95% confidence interval [CI]: 0.073–0.747; p = 0.014). By 12-month follow-up, DTC >4 hours was no longer associated with BCVA in a statistically significant manner (OR: 0.472; 95% CI: 0.135–1.653; p = 0.240). A similar trend was found at a DTC cutoff of ≥3 hours. None of the other studied parameters, including DTP, TIP, donor age, or medical history were significantly correlated with transplantation outcomes.

Singh R, Gupta N, Vanathi M, Tandon R. Corneal transplantation in the modern era. Indian J Med Res. 2019 Jul;150(1):7-22. doi: 10.4103/ijmr.IJMR_141_19. PMID: 31571625; PMCID: PMC6798607. : Corneal blindness is one of the major causes of reversible blindness, which can be managed with transplantation of a healthy donor cornea. It is the most

successful organ transplantation in the human body as cornea is devoid of vasculature, minimizing the risk of graft rejection. The first successful transplant was performed by Zirm, and since then, corneal transplantation has seen significant evolution. It has been possible because of the relentless efforts by researchers and the increase in knowledge about corneal anatomy, improvement in instruments and advancements in technology. Keratoplasty has come a long way since the initial surgeries wherein the whole cornea was replaced to the present day where only the selective diseased layer can be replaced. These newer procedures maintain structural integrity and avoid catastrophic complications associated with open globe surgery. Corneal transplantation procedures are broadly classified as full-thickness penetrating keratoplasty and partial lamellar corneal surgeries which include anterior lamellar keratoplasty [sperficial anterior lamellar keratoplasty (SALK), automated lamellar therapeutic keratoplasty (ALTK) and deep anterior lamellar keratoplasty (DALK)] and posterior lamellar keratoplasty [Descemet stripping automated endothelial keratoplasty (DSAEK) and Descemet membrane endothelial keratoplasty (DMEK)] broadly.

Gómez-Benlloch, A., Montesel, A., Pareja-Aricò, L., Mingo-Botín, D., Michael, R., Barraquer, R.I. and Alió, J. (2021), Causes of corneal transplant failure: a multicentric study. Acta Ophthalmol, 99: e922-e928. https://doi.org/10.1111/aos.14708 : Our research included a cohort of 571 keratoplasty failures, of which 509 met the inclusion criteria. The analysis of the causes of the PK failure showed that immunological allograft rejection represented the main cause, with 28.2% of the failures, followed by surface diseases (17.8%) and endothelial decompensation without rejection (17.3%). For the PK re-grafts group, the main cause of failure was immunological allograft rejection (34.0%), followed by diseases of the ocular surface (18.5%). For the DALK group, the failures mainly occurred due to surface diseases such as limbal stem cell insufficiency, infectious keratitis, keratolysis or persistent epithelial defect (37.8%). However, the main reason for failure in the DSAEK group was endothelial decompensation without rejection (31.9%) while primary graft failure was the main cause of failure in the DMEK group (64.1%).

Nishisako S, Yamaguchi T, Hirayama M, Higa K, Aoki D, Sasaki C, Noma H, Shimazaki J. Donor-Related Risk Factors for Graft Decompensation Following Descemet's Stripping Automated Endothelial Keratoplasty. Front Med (Lausanne). 2022 Feb 4;9:810536. doi: 10.3389/fmed.2022.810536. PMID: 35252249; PMCID: PMC8889573.: To identify donor-related risk factors associated with graft endothelial failure and postoperative endothelial cell density (ECD) reduction after Descemet's stripping automated endothelial keratoplasty (DSAEK). The median age of

the patients was 73.5 years (male; 35.6%). After DSAEK, ECD decreased from 2,674 cells/mm^2 (95% confidence interval [CI]; 2,646-2,701) to 1,132 (1,076-1,190) at 12 months and 904 (845-963) at 24 months ($P < 0.001$). Fifty-five eyes (9.4%) had graft endothelial failure without rejection. This failure was associated with donor pseudophakic lens status (hazard ratio [HR]; 2.67, CI; 1.50-4.76, $P = 0.001$) and preoperative endothelial folds (HR; 2.82, CI; 1.20-6.62, $P = 0.02$). The incidence of graft endothelial failure in non-FECD patients was significantly higher among those receiving donor grafts with a pseudophakic lens status and preoperative presence of endothelial folds ($P < 0.001$). Postoperative ECD loss was significantly greater in eyes with these risk factors compared to those without ($P = 0.007$).

MATERIAL AND METHODS

- **Organisation:** Department of Ophthalmology, Santosh Medical College and Hospital, Ghaziabad

- **Study Setting:** OPD based study

- **Type of Study**: Ambispective observational Study

- **Sample Size**: 68

- **Formula:**

$$n = \frac{Z^2 p(1-p)}{e^2}$$

n= Sample size
p= Relative prevalence (0.75)
z= Score determined on the basis of confidence level (e.g. z=1.65 for confidence level 90%)
e= Margin of error (0.1)

- **Study population**: Patient attending eye OPD at Santosh hospital.

Inclusion criteria-

- Patients who are showing signs of Graft failure post keratoplasty.

Exclusion Criteria

- Sclera extension
- Posterior segment involvement
- Patients not willing to give consent for the study

Methodology for Data Collection

- **HISTORY**
  - a comprehensive record will be compiled, encompassing details such as the patient's identity (including name, age, gender, occupation, and residence). A thorough clinical history will be documented, focusing on the onset, duration, progression, and any accompanying conditions of the patient's symptoms. Additionally, inquiries will be made regarding any prior incidents of injury or ocular surgeries, and any symptoms affecting the other eye will be noted down.
- **Visual Acuity**
  - Snellen's best corrected and uncorrected visual acuity must be recorded on each visit which is a good indicator of graft clarity or graft rejection. Visual acuity is a valuable tool to monitor the response to treatment.
- **Intraocular Pressure**
  - Secondary glaucoma is a vital complication post corneal transplantation. On every visit, intraocular pressure must be recorded. The preferred method would be a non-contact tonometer to avoid contact with the transplanted tissue and prevent any incidence of graft rejection or dehiscence
- **Retinoscopy and Refraction**
  - This is important to know the best-corrected visual, the spherical and cylindrical add needed, the amount of astigmatism induced due to sutures, and the spherical equivalent.
- **Anterior Segment Optical Coherence Tomography**
  - Useful to assess the depth of opacity, any areas of thinning, and graft attachment in DSEK and DMEK.

❖ **Fluorescein Staining**

- To rule out any epithelial defect, dry eyes, and ocular surface staining.

❖ **Macular Optical Coherence Tomography**

- This investigation will be helpful to rule out cystoid macular edema and epiretinal membrane.

❖ **INVESTIGATIONS**

Comprehensive investigations and screenings will be conducted, encompassing:

- Blood pressure assessment and fasting and post prandial blood sugar testing.
- Blood grouping, Complete blood count and Erythrocyte Sedimentation Rate will be done Conjunctival swab to be collected from recipients' eye before surgery.
- Additionally, histopathological examination of excised corneal tissues of recipients and donor will be carried out as part of the diagnostic process.

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❖ **MANAGEMENT**

- The prevention can be divided into preoperative, intraoperative, and postoperative risk factors for graft rejection.
- The management of corneal graft rejection rests on prompt detection and aggressive steroid therapy.
- It is important to counsel the patient to present immediately if any symptoms of graft rejection like pain, redness, and decreased vision are noticed.
- cycloplegic eye drops wherever necessary. treatment for cornea graft rejection is treating and preventing an episode of immune-mediated graft rejection.
- Immunomodulators

Follow up

- After surgery- full ocular examination will be done on day 1, 3, 7, 15 and months 1 , 3, 6 and 12 to look for any graft failure sign.

Reference Study

Gurnani B, Czyz CN, Mahabadi N, et al. Corneal Graft Rejection. [Updated 2023 Jun 11]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK519043/

STATISTICAL ANALYSIS

- The data will be collected and entered in MS excel 2010. Different statistical tools will be performed to analysis the data using STATA MP-17.
- Normally distributed data will be analyzed using parametric tests and non - normally distributed data will be analyzed using non parametric tests.
- Descriptive statistics will use for quantitative and categorical variables.
- Graphical representation of the variables will be shown to understand the results clearly.
- Correlation will be estimated to measure the strength of relationship between two or more quantitative variables.

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11. Bafna RK, Kalra N, Asif MI, Lata S, Rathod A, Balaji A, Sharma N. Suturing large therapeutic corneal grafts based on donor size: A simplified technique for the novice corneal surgeon. Eur J Ophthalmol. 2021 May;31(3):1417-1421. doi: 10.1177/1120672120974285. Epub 2020 Nov 23. PMID: 33228422.
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MASTER CHART

Demographic profile of recipient					Donor Factor				Preoperative factors				Post operative factors			Follow Ups:
Patient UHID	Age	Gender	Occupation	Blood Group	Age	Gender	Cause of Death	Blood Group	Diagnosis	Ocular surface	Previous Ocular Surgeries	Systmic health	Infections / Inflamations	Signs of rejection		

Consent

Dr. Animesh Singh has explained about the risk and procedure. I volunteer to take part in the study entitled "***Evaluation of The Risk Factor Of Corneal Graft Failure In Patients Undergoing Keratoplasty*** "and have also been explained the purpose of the study to my satisfaction. You are being requested to take part in a study entitled ***Evaluation of The Risk Factor Of Corneal Graft Failure In Patients Undergoing Keratoplasty***

VOLUNTARY PARTICIPATIONS

Your participations in this study is entirely voluntary and you are free to withdraw from this study as and you feel so.

RISK (IF ANY)

Adequate care will be taken if patient faces any adverse effect with the drug being used during study.

FORM

I.....S/o/D/o.....R/o..... ..... has been explained by.

I hereby give my consent to be enrolled in the study.

Santosh Medical College and

Hospital Informed Consent

I.....S/D/W of.....
Resident of.....

Hereby declare that I give my full and free & voluntary informed consent in the thesis entitled **"EVALUATION OF THE RISK FACTOR OF CORNEAL GRAFT FAILURE IN PATIENTS UNDERGOING KERATOPLASTY"**

Dr. Animesh Singh as informed to me to my full satisfaction, in the language I understand about the purpose and nature of the study & various physical examinations by the study to be carried out. I have been informed about the duration of the study and instructions to be followed during the study period. I give full consent for being enrolled in the above study and I reserve my rights to withdraw from the study whenever I wish prejudice of my right to undergo further treatment at Santosh Hospital Ghaziabad U.P.

Signature of Attending

Name Signature Of Patient

Relationship with patient

सन्तोष मेडिकल कॉलेज और अस्पताल
सूचित सहमति

मैं..... ., पुत्र / पुत्री / पत्नी
……,निवासी ……. इसके द्वारा घोषणा करता हूं कि मैं पूर्णऔ स्वतंत्रऔर स्वैच्छिक रूप सेऔ थीसिसअॅ किशोरों में शुष्क आंखों की व्यापकताल् **EVALUATION OF THE RISK FACTOR OF CORNEAL GRAFT FAILURE IN PATIENTS UNDERGOING KERATOPLASTY**, डॉ अनिमेष सिंह मेरी भाषा में अध्ययन के उद्देश्य और प्रकृति और विभिन्न शारीरिक परीक्षाओंकी प्रकृति के बारे में सूचित किया है। मुझे अध्ययन की अवधि औरअध्ययन की अवधि के दौरान दिए जाने वाले निदेर्शों के बारे में सूचितकिया गया है।मैं उपरोक्त अध्ययन में नामांकित होने के लिए पूर्ण सहमति देता हूं औरजब भी मैं आगेकेइलाज को जारी नहीं रखना चाहता हूंऔ तो मुझेअध्ययन से हटने काअधिकार है।

हस्ताक्षरी प्रतिभागी

नामी

दिनांक:

फ़ोन नंबर:

हस्ताक्षर: संरक्षक

नामी

दिनांक: